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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,185	11/11/1999	RICHARD S STEPHENS	018941-00041	8996

20350 7590 01/14/2003

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/14/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/438,185	Stephens
Examiner	**Art Unit**
Patricia A. Duffy	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 22, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *23-34* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *23-28* is/are allowed.

6) ☒ Claim(s) *29-34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-22-02 has been entered.

2. The amendment has been entered into the record. Claims 23-34 are pending and under examination.

3. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Specification

4. The disclosure is objected to because of the following informalities: at page 37, line 4, describing cpn0004 is not legible and at page 123, lines 3-5 apparently describing tRNAs is not legible. Legible substitute pages are required to correct this problem.

Further a review of the record indicates that the paper copy of sequence listing pages 1-1319 filed with the amendment of March 5, 2002 is not present in the file. A second copy of the sequence listing is required in order to complete the file record.

Rejections Maintained

5. Claims 29-34 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession

of the claimed invention is maintained for reasons made of record for claims 17-22 in Paper No. 15, mailed 5-21-02.

Applicants argue that pages 12-18 in combination with page 21, lines 24-25 provide for conception of expression of polypeptides from hybridizing nucleic acids. This is not persuasive, at pages 12-18 the discussion is directed to the use of the nucleic acids to identify hybridizing nucleic acids, PER and detection of sequences. This is not the same as using the hybridizing nucleic acids to produce a protein. The entirety of the section at page 12-18 is directed to using the nucleic acid as a probe/primers in hybridization based assays to diagnose the presence of *C. pneumoniae* nucleic acids in a sample. There is no conception of using the detected or nucleic acids that hybridizing to the nucleic acid of the invention in the cited sections for the production of polypeptides. The reference at page 21, teaches that "The nucleic acids disclosed here can be used for recombinant expression of the proteins.", however no hybridizing nucleic acids are disclosed in pages 12-18. Further, hybridizing nucleic acids to the coding strand provide for anti-sense nucleic acids that bear no structural relationship to the forwardly coded polypeptide. As such, the cited passages represent a combination of distinct concepts, the combination of which provides for a genus of encoding nucleic acids that lack conception by way of written description in this specification as filed.

Applicants arguments have been carefully considered but are not persuasive to remove the rejection of record.

6. Claims 29-34 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons made of record for claims 17-22 in Paper No. 15,

mailed 5-21-02. *This is a written description rejection.*

Applicants response has been carefully considered but is not persuasive to remove the rejection of record. Applicants argue that they have amended the claims to specify the enzymatic activity in addition to having a percent identity or being encoded by nueclotides hybridizing under specific conditions. This is not persuasive, the current claim construction provides for the combined properties of (I) and (ii) or (iii). This claim language does not support the asserted combination of (I) and (ii) or (I) and (iii). Therefore, Applicants arguments are not fully persuasive because the hybridizing variants do not have to have tryptophan hydroxylase activity and as such the claimed polypeptides encompassed by hybridizing variants are not required to have tryptophan hydroxylase activity.

The rejection is maintained over polypeptides that are encoded by embodiment (iii) alone.

7. Claims 29-34 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO:1047 and associated compositions, the specification does not reasonably provide enablement for 80% identical variants of SEQ ID NO:1047 that have tryptophan hydroxylase activity, or polypeptides encoded by nucleic acid sequences that hybridize to a sequence consisting of residues 1200537-1201343 of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims is maintained for reasons made of record for claims 17-22 in Paper No. 15, mailed 5-21-02.

Applicants response has been carefully considered but is not persuasive to remove the rejection of record. Applicants argue that they have amended the claims to specify the enzymatic activity in addition to having a percent identity or being encoded by nueclotides hybridizing under

specific conditions. This is not persuasive, the current claim construction provides for the combined properties of (I) and (ii) or (iii). This claim language does not support the asserted combination of (I) and (ii) or (I) and (iii). Therefore, the previous enablement rejection as it applied to hybridizing nucleic acids not linked by structure and function is maintained. The previous rejection also provides evidence of reason to doubt the alleged function assigned to the polypeptide of SEQ ID NO:1047 as a "tryptophan hydroxylase" (see page 7 of the previous office action) as is now claimed. The assignment of a proteins function based on fractional homology with other sequences was in doubt and remains in doubt, is fully supported by Applicants own specification at page 35, lines 15-17:

> "Although the chlamydial protein is similar to proteins of this family and incrementally more closely related to tryptophan hydroxylase, it specific function could not be confidently predicted."

Additionally, at page 35, the specification teaches that no other bacteria have these enzymes. Therefore, these statements in combination with the evidence provided by the examiner in the previous enablement rejection of record, provides a substantial reason to doubt that truth of the asserted function of SEQ ID NO:1047 as a tryptophan hydroxylase, in the absence of convincing factual evidence to the contrary. Therefore, Applicants clearly do not meet the standard for enablement in the claims as amended for these claims. Applicants urge that screening for 80% variants or hybridizing variants with tryptophan hydroxylase activity would be routine in the art and therefore not undue experimentation. This is not persuasive there is no evidence of record that SEQ ID NO:1047 actually functions as a tryptophan hydroxylase and substantial reason to doubt that it does. Further no assay to screen for variants has been set forth in the specification as filed. That the substrate and product of an enzymatic reaction are known, does not set provide

evidence that a screening assay for detection of enzymatic activity was available to the skilled artisan at the time of filing. Even if Applicants were to bring in evidence of an assay for tryptophan hydroxylase activity know to the art before the invention was made, there is reason to doubt that the polypeptide of SEQ ID NO:1047 functions as a tryptophan hydroxylase and therefore no screening assay would be able to detect activity of something that does not possess the activity in the first place. Consequently, one could not routinely screen for variants of a polypeptide that has not been demonstrated to have the claimed enzymatic activity.

The rejection is maintained.

Claim Rejections - 35 U.S.C. § 102 and 103

8. Applicants point to page 95, for support for the sequence of SEQ ID NO:1047, while it appears that the sequence of SEQ ID NO:1047 and it corresponding nucleic acid sequence is provided for, conception by way of written description of the claimed invention: 80% identical variants of the polypeptide and hybridizing variants of the polypeptide are not provided for in the text or claims of the 60/108,279. Applicants are directed *to Studiengesellschaft Khole m.b.H. v. Shell Oil Co.* 42 USPQ2d 1674 CAFC, 1997 which states:

> "In order for patent application to receive benefit of earlier filing date from prior application pursuant to 35 U.S.C. 120, earlier-filed applicant must contain disclosure which complies with first paragraph of 35 U.S.C. 112 for each claim in newly filed application, claim therefore complies with section 120 and acquires earlier filing date only if it could have been added to earlier application without introducing new matter."

Since these claims could not have been entered in the priority application without receiving a new matter rejection, the priority document fails to support the now claimed invention under 112, first paragraph.

9. Claim 29 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by PIR_68 Database Accession Number E72002, dated 23 April 1999.

Accession Number E72002 teaches a polypeptide that has 99.8% identity with the polypeptide of SEQ ID NO:1047. As such, this reference anticipates Markush member (I) of claim 29. Given the extensive homology, the polypeptide inherently possesses the claimed activities (hybridizing and enzymatic).

10. Claim 29-33 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by Griffais, R (WO 99/27105, published 03 June 1999) as represented by Genseq_0601 Database Accession Number AAY35703 attached hereto.

Griffais teaches a polypeptide from *Chlamydia pneumoniae* that has 91.8 % similarity and 66.2 % identity with SEQ ID NO:1047 and is 100% identical across greater than 200 consecutive amino acids (see attached alignment). The polynucleotide encoding this highly similar protein as taught by Griffais (see attached alignment) would hybridize with residues 1200537 to 1201343 of SEQ ID NO:1. Given the extensive homology, the polypeptide inherently possesses the claimed activities (hybridizing and enzymatic). Griffais contemplates polypeptides encoded by a polynucleotide sequence that hybridizes to SEQ ID NO:1 or an open reading frame thereof (see page 14, first full paragraph). As such, this reference meets the limitation of Markush member (ii) of claim 29. Further, Griffais teaches the isolated polypeptide in a composition comprising a pharmaceutically acceptable carrier or an adjuvant (see page 68, lines 25-35, page 70, lines 32-35). Griffais teaches the attachment of polypeptides to a chip (i.e. the instant solid phase; see page 283, Claim 31). Griffais et al also teach that the polypeptides of the invention may be use in a method of detection or the identification of bacteria belonging to the species of *Chlamydia pneumoniae* (see page 59, first full paragraph). Griffais also teaches that the protein may be any conventional

procedure for the detection of any antigen/antibody complexes that may be formed such as, ELISA and deposition of the protein on the microtiter plate (i.e. solid surface). These teachings anticipate claims 29-33.

11. Claim 34 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Griffais, R (WO 99/27105, published 03 June 1999) as represented by Genseq_0601 Database Accession Number AAY35703 in view of Catty et al (Antibodies, Vol II, A Practical Approach, IRL Press at Oxford University Press 1989, pages 97-154.

Griffais is set forth *supra*. Griffais differs by not attaching the protein of interest to nitrocellulose.

Catty et al teaches that a variety of solid phase surfaces have been exploited for ELISA assays, including nitrocellulose (see page 97, last line of first paragraph).

It would have been prima facie obvious to substitute the nitrocellulose solid phase for the microtiter plate solid phase of Griffais because Griffais teaches that the protein of interest can be used in any procedure for the detection of antigen/antibody complexes such as ELISA and Catty et al teach that nitrocellulose is a conventional solid phase carrier for dot-ELISA assays.

12. Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffais, R (WO 99/27105, published 03 June 1999) as represented by Genseq_0601 Database Accession Number AAY35703 in view of PIR_68 Database Accession Number E72002, dated 23 April 1999.

Griffais is set forth *supra*. Griffais differs by not teaching a protein that has 80% identity with SEQ ID NO:1047.

PIR_68 Database Accession Number E72002, dated 23 April 1999 teaches a polypeptide from *Chlamydia pneumoniae* that is 99.8% identical with SEQ ID NO:1047.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time

that the invention was made to substitute the protein of PIR_68 Database Accession Number E72002 from *Chlamydia pneumoniae* for any of the *Chlamydia pneumoniae* polypeptides and compositions of Griffais because Griffais teaches the polypeptides are useful in detection of infection an making antibodies for detection of the *Chlamydia pneumoniae* microorganism.

13. Claim 34 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Griffais, R (WO 99/27105, published 03 June 1999) as represented by Genseq_0601 Database Accession Number AAY35703 in view of PIR_68 Database Accession Number E72002, dated 23 April 1999 as applied to claims 18-21 supra, further in view of Catty et al (Antibodies, Vol II, A Practical Approach, IRL Press at Oxford University Press 1989, pages 97-154.

Griffais and PIR_68 Database Accession Number E72002 are set forth supra. The compositions as combined differ by not teaching nitrocellulose as a solid phase.

Catty et al teaches that a variety of solid phase surfaces have been exploited for ELISA assays, including nitrocellulose (see page 97, last line of first paragraph).

It would have been prima facie obvious to substitute the nitrocellulose solid phase for the microtiter plate solid phase of Griffais and PIR-68 Accession Number E72002 as combined *supra* because Griffais teaches that the protein of interest can be used in any procedure for the detection of antigen/antibody complexes such as ELISA and Catty et al teach that nitrocellulose is a conventional solid phase carrier for dot-ELISA assays.

Status of Claims

14. Claims 29-34 stand rejected. Claims 23-28 are allowed

Conclusion

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.
January 9, 2003

Pat a. Duffy

Patricia A. Duffy, Ph.D.
Primary Examiner
Group 1600